

determining a clearance profile for the radiopharmaceutical or a radiopharmaceutical analog;
determining the patient's mass and maximum effective mass;
selecting the lower of the patient's mass and maximum effective mass;
determining activity hours for the radiopharmaceutical or radiopharmaceutical analog based on the lower of the patient's mass or maximum effective mass and the desired total body dose;
determining residence time of an administered tracer dose of the radiopharmaceutical or the radiopharmaceutical analog in the whole body of the patient, the residence time being correlated to the clearance profile; and
establishing the optimally effective dose of the radiopharmaceutical for the patient by solving for therapeutic dose in the following equation:

B1

$$\text{therapeutic dose} = \frac{\text{Activity Hours}}{\text{Residence time}} \times \frac{\text{desired total body dose}}{\text{maximum tolerated dose.}}$$

B2
B3
Sub C4

4. (Amended) The method of claim 1, wherein the maximum effective mass is correlated to lean body mass of the patient.

19. (Amended) An optimally effective therapeutic dose of a radiopharmaceutical for administration to a patient, said optimally effective therapeutic dose determined by the method comprising:

determining a maximum tolerated dose for the radiopharmaceutical;
determining a desired total body dose of the radiopharmaceutical for the patient;
determining a clearance profile for the radiopharmaceutical or a radiopharmaceutical analog;
determining the patient's mass and maximum effective mass;
selecting the lower of the patient's mass and maximum effective mass;
determining activity hours for the radiopharmaceutical or radiopharmaceutical analog based on the lower of the patient's mass or maximum effective mass and the desired total body dose;

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determining residence time of an administered tracer dose of the radiopharmaceutical or the radiopharmaceutical analog in the whole body of the patient, the residence time being correlated to the clearance profile; and

establishing the optimally effective dose of the radiopharmaceutical for the patient by solving for therapeutic dose in the following equation:

$$\text{therapeutic dose} = \frac{\text{Activity Hours}}{\text{Residence time}} \times \frac{\text{desired total body dose}}{\text{maximum tolerated dose.}}$$

20. (Amended) A method of establishing a patient-specific optimally effective dose for administration of a radiopharmaceutical to a patient, the method comprising:

determining the desired total body dose (TBD) of the radiopharmaceutical for the patient;

determining the patient's mass (M) and maximum effective mass (MEM);

selecting the lower of the patient's mass and maximum effective mass (M or MEM);

determining activity hours (AH) for the radiopharmaceutical or a radiopharmaceutical analog by reference to Equation I:

$$AH = \frac{TBD \times (M \text{ or } MEM)}{\left[\sum_{elec} \Delta_{elect} + \sum_{phot} \Delta_{phot} \phi_{phot}^{TB} \right]}$$

(Equation I)

$$\text{where } \left[\sum_{elec} \Delta_{elect} + \sum_{phot} \Delta_{phot} \phi_{phot}^{TB} \right]$$

in Equation I represents the sum of electron energy and photon energy deposited in the total body of the patient by the radiopharmaceutical or radiopharmaceutical analog;

determining the patient-specific residence time of an administered tracer dose of the radiopharmaceutical or the radiopharmaceutical analog in the whole body of the patient;

and

establishing a therapeutic dose of the radiopharmaceutical for the patient by dividing the activity hours by the patient-specific residence time to obtain a value and optionally multiplying the value by an attenuation factor, said attenuation factor being determined by the TBD divided by the maximum tolerated dose for the radiopharmaceutical.

21. (Amended) The method of claim 20 further comprising the step of determining a clearance profile for the radiopharmaceutical or the radiopharmaceutical analog, said clearance profile providing a minimum number of time points for determination of the patient-specific residence time of the radiopharmaceutical or the radiopharmaceutical analog.

Please add claims 83 and 84 as follows:

83. The method of claim 1 wherein the radiopharmaceutical is an ^{131}I -labeled anti-B1 antibody.

84. The method of claim 19 wherein the radiopharmaceutical is an ^{131}I -labeled anti-B1 antibody.

REMARKS

Claims 1-24 remain in this application. Claims 13-18 and 22-24 are withdrawn from consideration pending allowance of a generic claim. Claims 1, 4, and 19-21 are amended. Claims 25-82 are canceled, without prejudice.

Claims 83 and 84 are added. Support for claims 83 and 84 can be found, *inter alia*, at page 13, and the Example beginning at page 32. These claims do not introduce new matter to the application.

Claim 19 is amended to bring it into conformity with claim 1 by more clearly describing the step of determining the residence time. This amendment finds support in